

# PATENT COOPERATION TREATY

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MUSERLIAN, LUCAS AND MERCANTI LLP

**PCT**

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

|   |
|---|
| To:<br>MICHAEL N. MERCANTI<br>MUSERLIAN, LUCAS & MERCANTI, LLP<br>475 PARK AVENUE SOUTH<br>NEW YORK, NY 10016 |
|---|

|                                     |                    |
|-------------------------------------|--------------------|
| Date of mailing<br>(day/month/year) | <b>20 MAY 2005</b> |
|-------------------------------------|--------------------|

|  |   |   |  |
|--|---|---|--|
| Applicant's or agent's file reference<br><br>525.1089PCT |   | <b>IMPORTANT NOTIFICATION</b>                                   |  |
| International application No.<br><br>PCT/US04/18463      | International filing date (day/month/year)<br><br>10 June 2004 (10.06.2004) | Priority date (day/month/year)<br><br>11 June 2003 (11.06.2003) |  |
| Applicant<br><br>BPSI HOLDINGS, INC.                     |   |   |  |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

|  |  |
|--|--|
| Name and mailing address of the IPEA/ US<br>Mail Stop PCT, Attn: IPEA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Authorized officer<br>Kimberly D. Nguyen<br>Telephone No. 571-272-2402 |
|--|--|

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**PARALEGAL SPECIALIST**  
**GROUP 1500**  
*Dat*

Form PCT/IPEA/416 (January 2004)

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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |   |   |                       |
|--|---|---|-----------------------|
| Applicant's or agent's file reference<br>525.1089PCT   | <b>FOR FURTHER ACTION</b>   |   | See Form PCT/IPEA/416 |
| International application No.<br>PCT/US04/18463  | International filing date (day/month/year)<br>10 June 2004 (10.06.2004) | Priority date (day/month/year)<br>11 June 2003 (11.06.2003) |                       |
| International Patent Classification (IPC) or national classification and IPC<br>IPC(7): G06K 7/10 and US Cl.: 235/462.01 |   |   |                       |
| Applicant<br>BPSI HOLDINGS, INC.   |   |   |                       |

  

|  |  |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
|--|--|---|-----------|---------------------|--------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| <ol style="list-style-type: none"> <li>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</li> <li>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</li> <li>3. This report is also accompanied by ANNEXES, comprising:               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:                   <div style="margin-left: 20px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).                   <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.                 </div> </li> <li>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</li> </ol> </li> </ol> | <ol style="list-style-type: none"> <li>4. This report contains indications relating to the following items:               <table style="width: 100%; border: none;"> <tr> <td style="width: 5%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 25%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> </li> </ol> | <input checked="" type="checkbox"/>   | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/>  | Box No. I  | Basis of the report   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. II   | Priority  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. IV   | Lack of unity of invention  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/>  | Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. VI   | Certain documents cited   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. VII  | Certain defects in the international application  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>   | Box No. VIII   | Certain observations on the international application   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |

  

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| Date of submission of the demand<br>16 December 2004 (16.12.2004)  | Date of completion of this report<br>26 April 2005 (26.04.2005)  |
| Name and mailing address of the IPEA/ US<br>Mail Stop PCT, Attn: IPEA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Authorized officer<br>Kimberly D. Nguyen<br>Telephone No. 571-272-2402<br><div style="text-align: right;"> <b>DEBORAH A. THOMAS</b><br/> <b>PARALEGAL SPECIALIST</b><br/> <b>GROUP 1300</b><br/> <i>DUT</i> </div> |

Form PCT/IPEA/409 (cover sheet)(January 2004)

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/18463

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-14 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_

☒ the claims:

pages 15-17 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_

☒ the drawings:

pages 1-2 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_  
☐ the claims, Nos. \_\_\_\_\_  
☐ the drawings, sheets/figs \_\_\_\_\_  
☐ the sequence listing (*specify*): \_\_\_\_\_  
☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_  
☐ the claims, Nos. \_\_\_\_\_  
☐ the drawings, sheets/figs \_\_\_\_\_  
☐ the sequence listing (*specify*): \_\_\_\_\_  
☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/18463**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

|                               |                                   |     |
|-------------------------------|-----------------------------------|-----|
| Novelty (N)                   | Claims <u>2, 5, 9, 10, 23, 24</u> | YES |
|                               | Claims <u>1,3,4,6-8 and 11-22</u> | NO  |
| Inventive Step (IS)           | Claims <u>NONE</u>                | YES |
|                               | Claims <u>1-24</u>                | NO  |
| Industrial Applicability (IA) | Claims <u>1-24</u>                | YES |
|                               | Claims <u>NONE</u>                | NO  |

## 2. Citations and Explanations (Rule 70.7)

Claims 1, 3-4, 6-8, 11-22 lack novelty under PCT Article 33(2) as being anticipated by Nellhaus et al. (US 6,543,692; hereinafter "Nellhaus").

Nellhaus teaches an oral solid dosage form (72 in fig. 10), comprising

a core portion having sufficiently low friability to receive a printed or etched marking on a surface thereof;

a readable printed or etched marking on the surface of the core, the marking providing identification/authentication of the oral dosage form (column 4, lines 25+).

Claims 2, 5, 23-24 lack an inventive step under PCT Article 33(3) as being obvious over Nellhaus in view of Sullivan et al. (US 5,992,742; hereinafter "Sullivan").

Sullivan teaches pill printing and identification having a pill, which has a film (a protein based film) coated prior to the printed or etched marking being applied thereto (column 5, lines 22+, column 11, lines 36+).

Claims 9-10 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Jain et al (US 6,316,029; hereinafter "Jain").

Jain teaches an oral dosage form having covert marking is detectable by aroma or taste (col. 1, lines 46+).